

JFW



Attorney Docket No.: P-4595-US2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): STEINER, Mitchell S. et al.

Examiner: Not yet known.

Serial No.: 10/747,691

Group Art Unit: 1615

Filed: December 30, 2003

Title: METHODS FOR TREATING HOT FLASHES AND GYNECOMASTIA

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO-1449:

1.  listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents, and/or United States patent applications, and/or United States patent application publications are not included in this information disclosure statement; and/or
2.  listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. 10/305,363, filed November 27, 2003 which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3.  listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;

APPLICANTS: STEINER, Mitchell S. et al.  
SERIAL NO.: 10/747,691  
FILED: December 30, 2003  
Page 2

4.  listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

I)  Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or

II)  After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1.  the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to

APPLICANTS: STEINER, Mitchell S. et al.  
SERIAL NO.: 10/747,691  
FILED: December 30, 2003  
Page 3

the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

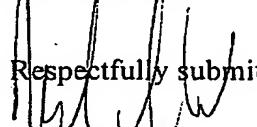
2.  the undersigned hereby authorizes the Patent Office to charge the fee in the amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 05-0649.

III)  After the period in (I) and (II) but before the payment of the issue fee and,

1. The undersigned hereby states:
  - a)  that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or
  - b)  that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and
2.  The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 05-0649.

APPLICANTS: STEINER, Mitchell S. et al.  
SERIAL NO : 10/747,691  
FILED: December 30, 2003  
Page 4

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 05-0649.

  
Respectfully submitted,  
\_\_\_\_\_  
Mark S. Cohen  
Attorney for Applicant(s)  
Registration No. 42,425

Dated: October 31, 2004

**Eitan, Pearl, Latzer & Cohen Zedek, LLP.**  
10 Rockefeller Plaza, Suite 1001  
New York, New York 10020  
Tel: (212) 632-3480  
Fax: (212) 632-3490

Please type a plus sign (+) inside this box →

+

NOV 15 2004

Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Do not collect a fee for this application unless it displays a valid OMB control number

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

<p>Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p><i>(use as many sheets as necessary)</i></p>		<b>Complete if Known</b>	
		Application Number	10/747,691
		Filing Date	December 30, 2003
		First Named Inventor	STEINER, Mitchell S.
		Group Art Unit	
		Examiner Name	
Sheet	of	Attorney Docket Number	
		P-4595-US2	

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U S Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231  
**DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231

Please type a plus sign (+) inside this box →  +

O P E JC98  
NOV 15 2004

PTO/SB/08A (10-96)

Approved for use through 10/31/99 OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<p>Substitute for form 1449B/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p><i>(use as many sheets as necessary)</i></p>			<b>Complete if Known</b>	
			Application Number	10/747,691
			Filing Date	December 30, 2003
First Named Inventor	STEINER, Mitchell S.			
Group Art Unit				
Examiner Name				
Sheet	of		Attorney Docket Number	P-4595-US2

<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	H	O'Brien Frank M. et al "Insulin-like Growth Factor I and Prostate Cancer", 2001 Elsevier Science Inc, Urology 58:1-7, 2001	<input type="checkbox"/>
	I	Horwitz Eric M. et al "Subset Analysis of RTOG 85031 and 86-10 Indicates An Advantage For Long-Term vs. Short-Term Adjuvant Hormones For Patients With Locally Advanced Nonmetastatic Prostate Cancer Treated with Radiation Therapy", Int. J. Radiation Oncology Biol. Phys. Vol. 49, No. 4 pp. 947-956, 2001, Elsevier Science Inc.	<input type="checkbox"/>
	J	Messing Edward M. et al "Immediate Hormonal Therapy Compared With Observation After Radical Prostatectomy and Pelvic Lymphadenectomy in Men With Node-Positive Prostate Cancer" The New England Journal of Medicine, 1999 Vol. 341, No. 24	<input type="checkbox"/>
	K	Newling Don W.W. "Early Versus Late Androgen Deprivation Therapy in Metastatic Disease" Elsevier Science Inc, Urology 58 (supplement 2A), August 2001	<input type="checkbox"/>
	L	Jordan Craig V. "Antiestrogenic Action of Raloxifene and Tamoxifen: Today and Tomorrow" Journal of National Cancer Institute, Vol. 90, No. 13, July 1, 1998	<input type="checkbox"/>
	M	Buelke-Sam J. et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology And Reproductive And Developmental Testing", Reprod Toxicol 1998 May-June; 12(3):217-21.	<input type="checkbox"/>
	N	Stege Reinhard et al. "Potential Side-Effects of Endocrine Treatment of Long Duration in Prostate Cancer" The Prostate Supplement 10:38-42, 2000	<input type="checkbox"/>
	O	Goodson Max J. "Dental Applications" Vol. II, Chapter 6,	<input type="checkbox"/>

Examiner Signature	Date Considered
--------------------	-----------------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

Burden Hour Statement: This form is estimated to take 2 0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231  
DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS SEND TO: Assistant Commissioner for Patents, Washington, DC 20231